

06-28-02

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## EXPRESS MAIL CERTIFICATE

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PATENT TRADEMARK OFFICE

Docket No.: 5986/11147 US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Max Costa, Konstantin Salnikow and Herman Yee

Serial No.: 10/057,832

Art Unit: 1645

Confirmation No.: 1550

Filed: January 25, 2002

Examiner: To be assigned

For: METHODS AND COMPOSITIONS USING CAP43 PROTEINS AND NUCLEIC  
ACIDS TO DIAGNOSE AND TREAT CANCER AND OTHER DISORDERS

INFORMATION DISCLOSURE STATEMENT RECEIVED

JUL 3 2002

TECH CENTER 1600/2900

Hon. Commissioner of Patents and Trademarks  
Washington, DC 20231

Sir:

In order to comply with the duty to disclose information under 37

C.F.R. § 1.56, Applicants submit herewith an Information Disclosure Statement in  
accordance with 37 CFR §§ 1.97 and 1.98. In particular, Applicants submit  
herewith: (1) a Form PTO-1449 listing references for consideration by the  
Examiner; and (2) copies of references 1-12 cited therein.

It is believed that no fee is required for this submission as this Information Disclosure Statement is timely submitted in accordance with 37 C.F.R. §1.97(b)(3) and before any mailing of a first Office Action on the merits. However, should the U.S. Patent and Trademark Office determine that any fee is required or that any required is due for this application, the Commissioner is authorized and requested to change any required fee(s) and/or credit any refund(s) due to Deposit Account No. 04-0100.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration by the Examiner and that it be cited of record in the prosecution history of the present application by initialing Form PTO-1449 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

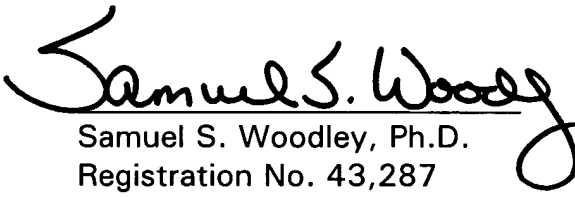
The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art.

No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

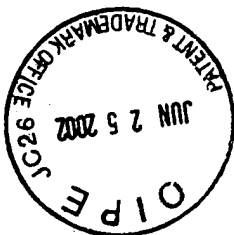
Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Dated: June 25, 2002

  
Samuel S. Woodley, Ph.D.  
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Agent for Applicant(s)

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT &amp; TRADEMARK OFFICE

**DRAFT****SHEET 1 OF 2**  
(REV. 7-80)**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 5986/11147US1      SERIAL NO: 10/057,832  
APPLICANT: Max Costa et al.      FILING DATE: January 25, 2002

**U.S. PATENT DOCUMENTS**

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>FILING DATE</u>
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**FOREIGN PATENT DOCUMENTS**

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>TRANSLATION YES      NO</u>
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**OTHER REFERENCES****(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)****\*EXAMINER  
INITIALS**

1. Murray *et al.*, "Tumor-specific Expression of Cytochrome P450 CYP1B1," *Cancer Research*, July 1997 57:3026-3031
2. Mushkkelishvili *et al.*, "In Situ Hybridization and Immunohistochemical Analysis of Cytochrome P450 1B1 Expression in Human Normal Tissues," *J. Histochem. Cytochem.*, Vol. 49(2):229-236, 2001
3. Zhou *et al.*, "Cap43, a Novel Gene Specifically Induced by Ni<sup>2+</sup>, Compounds<sup>1</sup>," *Cancer Res.*, May 15, 1998, 58:2182-2189
4. Salnikow *et al.*, "Role of Ca<sup>2+</sup> in the Regulation of Nickel-Inducible Cap43 Gene Expression," *Toxicology and Applied Pharmacology*, May 6, 1999, 160:127-132
5. Salnikow *et al.*, "A new Gene Induced by a Rise in Free Intracellular Ca<sup>2+</sup> Following Ni<sup>2+</sup> Exposure," *Metals and Genetics*, Chapter 8, (Sarker, Ed.) pp.131-144
6. Salnikow *et al.*, "Carcinogenic Nickel Induces Genes Involved with Hypoxic Stress," *Cancer Res.*, January 1, 2001, 60:38-41
7. Forsythe *et al.*, "Activation of Vascular Endothelial Growth Factor Gene Transcription by Hypoxia-Inducible Factor 1," *Mol. Cell. Biol.*, September 1996, 16: pgs. 4606-4613



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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

SHEET 2 OF 2  
(REV. 7-80)

**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 5986/11147US1

SERIAL NO: 10/057,832

APPLICANT: Max Costa et al.

FILING DATE: January 25, 2002

\*EXAMINER  
INITIALS

8. van Belzen *et al.*, "A Novel Gene Which Is Up-Regulated during Colon Epithelial Cell Differentiation and Down-Regulated in Colorectal Neoplasms," *Lab. Invest.*, July 1997, Vol. 77:85-92

9. Semenza *et al.*, "Hypoxia Response Elements in the Aldolase A, Enolase 1, and Lactate Dehydrogenase A Gene Promoters Contain Essential Binding Sites for Hypoxia-inducible Factor 1," *J. Biol. Chem.*, 1996) 271:32529-32537

10. Semenza, "Regulation of Mammalian O<sub>2</sub> Homeostasis by Hypoxia-Inducible Factor 1," *Annu. Rev. Cell. Dev. Biol.*, 1999, 15:551-578

11. Salnikow *et al.*, "Hyperinducibility of Hypoxia-responsive Genes without p53/p21-dependent Checkpoint in Aggressive Prostate Cancer<sup>1</sup>," *Cancer Res.*, October 15, 2000, 60: 5630-5634

12. Campbell, A., "General properties and applications of monoclonal antibodies," IN: *Monoclonal Antibody Technology*, 1984, Chapter 1:1-32

EXAMINER: \_\_\_\_\_

DATE CONSIDERED: \_\_\_\_\_

\*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.